510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Regulatory Affairs Specialist
Telephone No.: (714) 730-5000

K013633

NOV 1 3 2001

Device Proprietary Name: SSA-770A, Aplio Ultrasound System
Common Name: Diagnostic ultrasound system

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System - Procode: 90-IYN
[Fed.Reg.No.:892.1550]
Ultrasonic Pulsed Echo Imaging System - Procode: 90-IYO
[Fed.Reg.No.:892.1560]
Diagnostic Ultrasonic Transducer - Procode: 90-ITX
[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to the SSA-390A/PowerVision 8000, 510(k) control number K991858 and the UIDM-400A, 510(k) control number K992886.

Device Description:
The APLIO Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:
The APLIO is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial) and laparoscopic.

Safety Considerations:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601 (applicable portions), IEC601-2-37 (Draft), the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard. This unit is similar to that of the Toshiba SSA-390A/PowerVision 8000 and engineering assessments identify no unmitigated issues of risk or safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
TÜV Product Service
1775 Old Highway 8 NW
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013633
Trade Name: SSA-770A, APLIO Diagnostic System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: 90 IYN
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: 90 IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Product Code: 90 ITX
Regulatory Class: Class II
Dated: November 1, 2001
Received: November 5, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SSA-770A, APLIO Diagnostic System, as described in your premarket notification:

Transducer Model Number

PST-20CT
PST-25AT

PVT-375AT
PVT-661VT
PLT-805AT
PLT-1202S
PLT-1204AX
PET-510MB
PET-704LA
PC-20M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the

promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K013633

Diagnostic Ultrasound Indications For Use Form

System _X__ Transducer___
Model___SSA-770A_____
510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		n	n	n		n	n	n	n	n
Abdominal		n	n	n		n	n	n	n	n
Intraoperative (Specify)		n	n	n		n	n	n	n	
Intraoperative Neurological										
Pediatric		n	n	n	n	n	n	n	n	n
Small Organ (Specify)		n	n	n		n	n	n	n	n
Neonatal Cephalic		n	n	n	n	n	n	n	n	n
Adult Cephalic		n	n	n	n	n	n	n	n	n
Cardiac		n	n	n	n	n	n	n	n	n
Transesophageal		n	n	n	n	n	n	n	n	
Transrectal		n	n	n		n	n	n	n	n
Transvaginal		n	n	n		n	n	n	n	n
Transurethral										
Intravascular										
Peripheral Vascular		n	n	n		n	n	n	n	n
Laparoscopic		n	n	n		n	n	n	n	n
Musculo-skeletal Superficial		n	n	n		n	n	n	n	n
Musculo-skeletal Conventional		n	n	n		n	n	n	n	n
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

EXISTING TRANSDUCER TABLE

Transducer Model Number: PST-20CT
510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P	P	P	P
Adult Cephalic		P	P	P	P	P	P	P	P	P
Cardiac		P	P	P	P	P	P	P	P	P
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

EXISTING TRANSDUCER TABLE

Transducer Model Number: PST-25AT
510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P	P
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P	P	P	P
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVT-375AT
510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging)
Ophthalmic										
Fetal		P	P	P		P	P	P	P	P
Abdominal		P	P	P		P	P	P	P	P
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P	P
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVT-661VT

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P	P	P	P
Transvaginal		P	P	P		P	P	P	P	P
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF;BDF/MDF/PED; B-TDI; M-TDI; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Other: Harmonic Imaging (CHI, FEI)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLT-805AT

510(k) Control Number:

Clinical Application		Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P	P
Laparoscopic										
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLT-1202S

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)		P	P	P		P	P	P	P	
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P	
Laparoscopic										
Musculo-skeletal Superficial		P	P	P		P	P	P	P	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLT-1204AX

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P	
Laparoscopic										
Musculo-skeletal Superficial		P	P	P		P	P	P	P	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PET-510MB

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P	P	P	P	P	P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use (Per 21 CFR 801.109) 510(k) Number K013633

EXISTING TRANSDUCER TABLE

Transducer Model Number: PET-704LA

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		P	P	P		P	P	P	P	
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K013633

EXISTING TRANSDUCER TABLE

Transducer Model Number: PC-20M
510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric					P					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013633